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ABX-AE CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Liise-anne Pirofski et al.
Application No. : 10/714,079 Confirmation No. : 5765
Filed : November 14, 2003
For : HUMAN ANTIPNEUMOCOCCAL ANTIBODIES FROM
NON-HUMAN ANIMALS
Group Art Unit : 1614
Examiner : Not yet assigned

New York, New York
June 3, 2004

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Attn: Licensing and Review

**RESPONSE TO REQUIREMENT FOR STATEMENT
UNDER § 152 OF THE ATOMIC ENERGY ACT**

Sir:

This is in response to an April 23, 2004 Notice from the United States Patent and Trademark Office, Licensing and Review (hereafter "Notice"), a copy of which is enclosed. A response is due June 7, 2004. Thus, this response is timely filed.

REMARKS

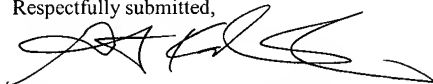
The Notice states that the applicants must file a statement within 45 days setting forth (1) the full facts concerning the circumstances under which the invention was made and conceived and (2) the relationship (if any) of the invention to the performance of any work under any contract or other arrangement with the Department of Energy. To

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satisfy the requirement, applicants enclose a Statement to Department of Energy signed by the inventors setting forth these facts.

The Director is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this response is enclosed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Gunnison', written over a horizontal line.

Jane T. Gunnison (Reg. No. 38,479)
Attorney for Applicants
Grant Kalinowski (Reg. No. 48,314)
Agent for Applicants

FISH & NEAVE
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1105
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Fax: (212) 596-9090

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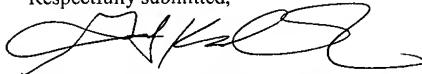
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Alexandria, Virginia 22313-1450

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STATEMENT TO DEPARTMENT OF ENERGY

We,

(1) Liise-anne Pirofski;

(2) Zhaojing Zhong; and

(3) Qing Chang;

all citizens of the United States of America; and

residing, respectively, at

(1) 180 East End Avenue, Apt. 12A

New York, NY 10128, U.S.A.;

(2) 1516 Seminole Avenue
Bronx, NY 10461, U.S.A.; and
(3) 1925 Eastchester Road, Apt. 16A
Bronx, NY 10461, U.S.A.;

hereby declare:

That we made and conceived the invention described and claimed in patent application Application Number 10/714,079, filed in the United States of America on November 14, 2003, and titled HUMAN ANTIPNEUMOCOCCAL ANTIBODIES FROM NON-HUMAN ANIMALS;

That we made and conceived this invention while employed by Albert Einstein College of Medicine of Yeshiva University;

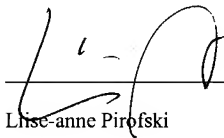
That the invention is related to work we were employed to perform and was made within the scope of our employment duties;

That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Albert Einstein College of Medicine of Yeshiva University;

That to the best of our knowledge and belief the invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into, with, or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

The undersigned inventors declare further that all statements made herein of their own knowledge are true and that all statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

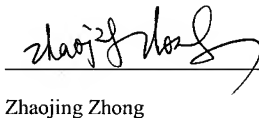
(1) Inventor's signature


Lise-anne Pirofski

5/31/04
Date

Post Office Address 180 East End Avenue, Apt. 12A, New York, NY 10128

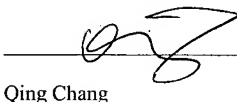
(2) Inventor's signature


Zhaojing Zhong

5/31/04
Date

Post Office Address 1516 Seminole Avenue, Bronx, NY 10461

(3) Inventor's signature


Qing Chang

5/17/04
Date

Post Office Address 1925 Eastchester Road, Apt. 16A, Bronx, NY 10461



IFW
UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/714,079	11/14/03	PIROFSKI, ET AL.	ABX-AE1 CON

FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

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ART UNIT	PAPER NUMBER

PATENT & TRADEMARK OFFICE

DATE MAILED:

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APR 23 2004

LICENSING & REVIEW

**IF NO RESPONSE TO THIS NOTICE IS RECEIVED WITHIN FORTY-FIVE DAYS, A
FORMAL REQUIREMENT WILL BE ISSUED**

The subject matter of this application appears to:

☒ be "useful in the production or utilization of special nuclear material or atomic energy" as recited in 42 U.S.C. 2182 (Department of Energy (DOE)).

☐ "have significant utility in the conduct of aeronautical and space activities" as recited in 42 U.S.C. 2457 (National Aeronautics and Space Administration (NASA)).

Accordingly, no patent can issue on this application unless applicant(s) file a statement (under oath or in the form of a declaration as provided by 37 CFR 1.68) setting forth: (1) the full facts concerning the circumstances under which the invention was made and conceived and (2) the relationship (if any) of the invention to the performance of any work under any contract or other arrangement with the Agency (ies) noted above. On the reverse side of this form is an example of an acceptable format for this statement. The language appearing in paragraphs III and/or IV of the example *must* appear if applicant is attempting to establish that no relationship (under item 2 above) exists.

If the invention disclosed in this application was developed under a contract, grant or cooperative agreement between the Agency indicated above and a person, small business or non-profit organization and rights to the invention have been determined by specific reference to 35 U.S.C. 202 in the contract, grant or cooperative agreement, then applicant need not submit the statement described above. Instead, applicant may file a verified statement (under oath or in the form of a declaration, 37 CFR 1.68) setting forth the information required by 35 U.S.C. 202(c)(6).

IF NO STATEMENT HAS BEEN RECEIVED WITHIN FORTY-FIVE DAYS OF THE MAIL DATE INDICATED ABOVE, a formal requirement for statement will then be issued. No provision is made for extension of the statutory thirty-day period for response to the formal requirement and the penalty for failure to file an acceptable and timely statement is abandonment of the application. Therefore, applicants are strongly encouraged to submit a statement at this time in order to avoid the issuance of a formal requirement.

IT IS IMPORTANT TO NOTE that the statement must accurately represent the property rights situation of the claimed invention if and when the application is found allowable. Thus, if during prosecution before the examiner, the claimed invention is so altered or the property rights situation so changed as to impact the accuracy of a statement submitted earlier, a supplemental statement must be filed. Failure to submit such additional information where appropriate may be considered a false representation of material facts and render the patent owner vulnerable to loss of patent rights and other sanctions as set forth in the statutes. The PTO will not review allowed applications for this possibility. The responsibility for complying with the statutes rests with the applicants.

Any questions regarding this requirement should be directed to Licensing and Review at 202-473-4441

(105) 305-0241

**PLEASE DIRECT ALL COMMUNICATIONS RELATING TO THIS MATTER TO THE
ATTENTION OF LICENSING AND REVIEW.**

FE230790705US

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Filed Date : November 14, 2003

Express Mail mailing label number EF230790705US

Date of Deposit June 3, 2004

I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Attn. Licensing and Review.



Claire J. Saint-Jean Goodman

Enclosures:

- 1) Response to Requirement for Statement Under § 152 of The Atomic Energy Act (in dupl.);
- 2) Copy of Notice;
- 3) Statement To Department of Energy.; and
- 4) Postcard.



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Grant Kalinowski
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New York, NY 10020
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TO: PLEASE PRINT

HON. COMM. JAMES H. HARRIS
Hon. Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450
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EP-13F February 2002

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